UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,134	01/28/2004	Donald J. Kerrish	61404-020	3590

7590 04/05/2007

McDermott, Will & Emery
600 13th Street, N.W.
Washington, DC 20005-3096

EXAMINER	
CRANE, LAWRENCE E	
ART UNIT	PAPER NUMBER
1623	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/765,134	KERRISH ET AL.	
	Examiner	Art Unit	
	L. E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *August 23, 2006 (amdt)*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 January 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08/23/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

No additional claims have been cancelled, claims **39, 42-43, 47, -49, 51-52 and 54-56** have been amended, new claims **57 and 58** have been added and the disclosure has been amended as per the amendment filed August 23, 2006. One supplemental Information Disclosure Statement (1 IDS) filed August 23, 2006 has been received with only one foreign patent reference and no references cited in the Non-Patent Literature section provided. Because copies of the Non-Patent Literature references were not supplied, these references were not considered. The amended drawing has been received and found acceptable as legible and ready for publication.

Claims **39-58** remain in the case.

Note to applicant: when a rejection or objection refers to a claim **X** at line y, the line number is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

Claims **39-58** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is reminded that a patent is granted in return for a disclosure of all of the details of an invention, see *Brenner v. Manson,* 148 USPQ 689 (S. Ct., 1966) at p. 696, column 1, "[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful completion." And in addition a patent is awarded in exchange for a complete disclosure of how the invention is practiced, a policy which, if not enforced, would probably lead to the wholesale patenting of trade secrets.

In this case the particular number and the particular identities of the excipients, and the particular conditions of their processing in the presence of ribavirin, represent the essence of the invention being claimed, but have only been claimed generically and have not been claimed in detail. A review of the instant claims and the instant disclosure suggest that presently applicant may not have made a complete disclosure and therefore may be attempting to patent a process portions of which have neither been disclosed nor claimed. Applicant is respectfully requested to supplement the instant disclosure as possible to fill in the details or to take other

appropriate actions (a CIP filing with a more complete disclosure is suggested as one possibility).

Applicant's arguments filed August 23, 2006 have been fully considered but they are not persuasive.

Applicant's amendments are noted, but are not deemed to be effective in overcoming this rejection. As noted in the rejection, the instant disclosure appears to require supplementation. The amendments supplied in applicant's response do not help overcome this problem.

Claims **39-58** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention; the scope is excessive in view of the disclosed exemplifications.

The failure to define the number of, or the particular identities of, the excipients in claims **39-56** renders the scope of the instant claims excessive in light of the specific embodiments. The instant claims are directed to a vast array of compositions only a very small proportion of which have been embodied herein. Narrowing of the scope of the claims to more nearly correspond to the scope of the enabled exemplifications is respectfully requested.

Applicant's arguments filed August 23, 2006 have been fully considered but they are not persuasive.

Applicant has not provided claims wherein the scope of the entire claim set is noticeably different. Therefore, the above grounds of rejection have been maintained.

Claims **39, 43, 47, 51 and 54-56** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim **39** the term "an excipient" renders the instant claim incomplete because the identity or the identities of the "excipient" has/have not been provided in the remainder of the claim. See also claims **43 and 49**. See also claim **47** wherein the term "a binder" has the same problem. See claims **51 and 56** which also fail to specifically identify the particular "excipient" referred to generically therein.

Applicant's arguments with respect to claims **39, 43, 47, 49, 51 and 56** have been considered but are moot in view of the new grounds of rejection. This new ground of rejection was necessitated by applicant's amendment.

Claim **54** is incomplete because, while said claim is directed to a process of formulation, it fails to provide any steps directed to how the claimed process is to be performed.

Applicant's arguments filed August 23, 2006 have been fully considered but they are not persuasive.

Examiner notes the amendment of claim **54** but does not see a completely described process. "Wet granulation" is a generic term but said term fails to be filled in with additional details including process conditions, excipients, and the other process variables common to all "wet granulation" processes.

Claim **55** is incomplete because it fails to provide the identity or identities of the substances which when added to ribavirin make up the remainder of the claimed composition.

Applicant's arguments filed August 23, 2006 have been fully considered but they are not persuasive.

Examiner notes the amendment provided by applicant but the term "excipient" does not identify the particular substances present in addition to ribavirin.

The non-statutory double patenting rejection, whether of the obvious-type or non-obvious type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thompson,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam,* 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi,* 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman,* 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. §§1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with the application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, an registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **39-54** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims *1-17* of U.S. Patent No. **6,720,000** (PTO-892 ref. **I**). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to processes for making ribavirin-containing pharmaceutical compositions by a process involving wet granulation in the presence of a variety of pharmaceutical carriers and excipients, wherein the patented process is encompassed by the instant claimed process.

Applicant's arguments filed August 23, 2006 have been fully considered but they are not persuasive.

Applicant has noticed this rejection but has not responded either with an argument overcoming same or with the requested Terminal Disclaimer. Therefore, the rejection has been maintained.

The following is a quotation of 35 U.S.C. §103(**a**) which forms the basis for all obviousness rejections set forth in this Office action:

> "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

Claims **39-54** are rejected under 35 U.S.C. §103(**a**) as being unpatentable over **Tam '097** (PTO-1449 ref. **A9**) in view of **Liebowitz et al.** (PTO-1449 ref. **A10**) and further in view of PTO-892 refs. **S (Rudnic) and T (Porter)**.

The instant claims are directed to a wet granulation/spheronization-spheronizing process of making a ribavirin-containing pharmaceutical composition using convention carriers and excipients.

Tam at column 4, lines 35-54 discloses multiple different variations of pharmaceutical compositions containing ribavirin as the active ingredient. **Tam** does not disclose any specific process details for the preparation of any pharmaceutical composition.

Liebowitz et al. is directed to ribavirin-containing pharmaceutical compositions which are fast dissolving and which include conventional carriers and excipients, and a process for conversion of said composition into a fast-dissolving compacted capsule form. **Liebowitz et al.** does not disclose "spheronized" ribavirin-containing compositions or the subsequent coating thereof.

Rudnic (PTO-892 ref. **S**) beginning at column 1 of page 1646 discloses "Spheronization" which appears to be the same as applicant's "spheronizing." Rudnic does not disclose "spheronized" ribavirin-containing compositions.

Porter(PTO-892 refs. **T**) discloses the coating of pharmaceutical dosages forms and at page 1666 at column 1 lists 9 reasons for using this technology in the preparation of pharmaceutical compositions. Porter does not disclose "spheronized" ribavirin-containing compositions which ave been further coated.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the disclosures cited because of the motivations provided by the Tam and Liebowitz references and because the variations claimed herein appear to be entirely conventional and to have not produced any unexpected results.

One having ordinary skill in the art would have been motivated to combine these references because Tam motivates the preparation of various pharmaceutical compositions and the remaining references provide details of how this may be accomplished in the manner claimed herein. In particular Liebowitz et al. provides a subsidiary motivation by disclosing the commonly used carriers and excipients. And lastly the chapters from Remington's Pharmaceutical Sciences provide details of how solid dosage forms may be prepared by various standard processes including spheronization, and how such pellets may be further process by addition of exterior coatings to effect rate of dissolution.

Therefore, the instant claimed process of producing ribavirin-containing pharmaceutical compositions using spheronized and optionally surface-coated pellets would have been obvious

to one of ordinary skill in the art having the above cited reference before him at the time the invention was made.

Applicant's arguments filed August 23, 2006 have been fully considered but they are not persuasive.

Applicant's claims remain very generic and are not accompanied by any declarations showing unexpected results. Therefore, in view of *Billman* (see below for cite), examiner is unable to see how applicant can overcome this rejection or the subsequent rejection.

Claims **55-56** are rejected under 35 U.S.C. §103(**a**) as being unpatentable over **Tam '097** (PTO-1449 ref. **A9**) in view of **Liebowitz et al. '128** (PTO-1449 ref. **A10**).

The instant claims are directed to compositions containing ribavirin.

Tam at column 4, lines 35-54 discloses multiple different variations of pharmaceutical compositions containing ribavirin as the active ingredient.

Liebowitz et al. is directed to ribavirin-containing pharmaceutical compositions which are fast dissolving and which include conventional carriers and excipients, and a process for conversion of said composition into a fast-dissolving compacted capsule form.

Applicant is also referred to *Ex Parte Billman* , 71 USPQ 253 (POBA 1946) wherein it is stated that "[whether]...the effective ingredient ... is carried by a solvent or a diluent does not change the effective character of the compound." This view is further supported by the more recent decision in *In re Rosicky* , 125 USPQ 341 (CCPA 1960) wherein it is stated that "A known compound in association with a carrier is not a patentable composition." In light of the guidance provided by the above noted prior board and court decisions and the disclosures of **Tam '097** and **Liebowitz et al. '128**, compositions containing ribavirin and one or more of the various notoriously well known in the art excipients or carriers would have been obvious to one of ordinary skill in the art in light of the teachings of both **Tam** and **Liebowitz**, which teachings are directed in part to making and isolating ribavirin-containing pharmaceutical compositions.

Therefore, the instant claimed ribavirin-containing compositions would have been obvious to one of ordinary skill in the art having the above cited reference before him at the time the invention was made.

See also **Rudnic et al. '014** (PTO-1449 ref. A24, column 11 at lines 25-35); **Johannesson et al. '669** (PTO-1449 ref. **A30**, see claims ***13-16***); **Smith et al. '265** (PTO-1449 ref. **A26**, see pp 6, line 22 to page 7, line 17 and, formulation and use in process of making claims ***1-32***); **Witkowski et al. '216** (PTO-1449 ref. **A3**, see ointments, creams and topical solutions at columns 5-7); **Witkowski et al. '545** (PTO-892 ref. **C**, see ointments, creams and topical solutions at columns 5-7); **Witkowski et al. '771** (PTO-1449 ref. **A7**, see ointments, creams and topical solutions at columns 4-8); **Liebowitz et al. '594** (PTO-1449 **A11**, see columns 2 and 6-8); **Liebowitz et al. '252** (PTO-1449 **A12**, see columns 2 and 6-8); **Liebowitz et al. '032** (PTO-1449 **A19**, see columns 2 and 6-10); and **Liebowitz et al. '090** (PTO-1449 **A20**, see the Bowen declaration).

Applicant's arguments filed August 23, 2006 have been fully considered but they are not persuasive.

Applicant is referred to the response following the previous rejection.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. §1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published

in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

LECrane:lec
04/02/2007

4/2/07

S. Anna Jiang, Ph.D.
Supervisory Patent Examiner
Technology Center 1600